



Docket No. 19301 US

*PATENT*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Bhullar et al.

Application No.: 09/866,030 Group No.: 1743

Filed: May 25, 2001 Examiner: Siefke, Samuel P.

For: Biosensor

**BRIEF OF BHULLAR ET AL.**

Commissioner for Patents  
P.O. Box 1450  
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Sir:

Appellants appeal the Final Rejection dated November 18, 2005 of claims 6, 10-15 and 21-26 of this application.

**STATUS OF THE CLAIMS**

The captioned application was filed as Serial No. 09/866,030 on May 25, 2001. The 19 claims in that initial filing were subjected to an election/restriction requirement: Group I – claims 1-15 drawn to a biosensor; Group II – claims 16-19 drawn to a method of making a biosensor. Group I, claims 1-15 were provisionally elected for prosecution. Claims 16-19 were withdrawn from consideration and subsequently cancelled. In response to the Office Action mailed September 22, 2003 and Reply to Notice of Non-Compliant Amendment mailed March 17, 2004, dependent claim 9 was cancelled and independent claim 20 and dependent claims 21-23 drawn to a biosensor were added. In response to the Office Action mailed January 11, 2005, independent claims 1, 8 and 20 along with dependent claims 2-5 and 7, were cancelled and independent claims 24-26 drawn to a biosensor were added. Claims 6, 10-15 and 21-26 are currently rejected and are being appealed.

## SUMMARY OF THE INVENTION

The present invention relates to a biosensor 10 (page 1 line 14). The biosensor 10 comprises a support 12 having first and second ends 28, 30 (page 1 lines 14-15; page 3 lines 12-16, page 4 lines 21-22; and Figure 2) and electrodes 14, 16, 18 positioned on the support 12 (page 1 lines 14-16; page 3 lines 1-3 and 26-27; page 4 lines 11-15; and Figures 2-4). The electrodes 14, 16, 18 cooperate with one another to define electrode arrays 76, 78 situated adjacent to the first end 28 of the support 12 (page 1 lines 16-17 and 21-22; page 4 lines 19-22; and Figures 2 and 3). The biosensor 10 further comprises a spacer 20 having individual members 40, 42, 44 (page 2 lines 20-23; page 4 line 28 to page 5 line 2; and Figure 2), and a cover 22 (page 1 line 18; page 2 lines 15-16; and Figures 1A, 1B and 2). The cover 22 cooperates with the support 12 to define a capillary channel 82 extending between the individual members 40, 42, 44 (page 1 lines 20-21; page 2 lines 20-23 and 30-33; page 6 lines 6-11; and Figures 1A, 1B, and 4). The channel 82 has opposing outlets 86 (page 6 lines 1-6 and Figure 1A and 1B) and a concave inlet 84 (page 6 lines 1-2; page 10 lines 11-14 and Figure 1A) extending from the first end 28 of the support 12 (page 1 lines 20-21 and Figure 1A) and being positioned between the opposing outlets 86 of the channel 82 (page 1 lines 27-29; page 2 lines 6-7; and Figures 1A and 4). Each electrode array 76, 78 is positioned in the channel 82 adjacent to one of the opposing outlets 86 (page 1 lines 21-22; page 5 lines 3-5; page 6 lines 9-11; and Figures 1B and 2).

Additionally, the present invention relates to a biosensor 10 (page 1 line 23). The biosensor comprises a support 12 having a first edge 28 (page 3 lines 12-16; page 4 lines 21-30; and Figures 1A and 2) and first and second electrode sets 14, 16 and 16, 18 positioned on the support 12 spaced-apart from one another (page 1 lines 23-26; page 3 lines 1-3 and 26-27; page 4 lines 11-15; page 9 lines 4-6; and Figures 2-4). The biosensor 10 further comprises a spacer 20 having individual members 40, 42, 44 (page 2 lines 20-23; page 4 line 28 to page 5 line 2; and Figure 2) and a cover 22 (page 1 line 18; page 2 lines 15-16; and Figures 1A, 1B and 2). The cover 22 has a second edge 62 (page 5 lines 20-24 and Figures 1A, 1B, and 2). The cover 22 extends across the first and second electrode sets 14, 16 and 16, 18 (page 1 lines 20-23, page 9 line 30 - page 10 line 17; and Figure 1B). The cover 22 also cooperates with the support 12 to define a generally linear capillary channel 82 (page 6 lines 1-2 and

Figures 1A and 1B) extending between the individual members 40, 42, 44 (page 6 lines 6-11 and Figures 1A and 1B). The channel 22 has opposing first and second outlets 86 (page 6 lines 1-6 and Figure 1A and 1B) and an inlet 84 aligned with the first edge 28 of the support 12 and the second edge 62 of the cover 22 (page 6 lines 1-2; page 10 lines 11-14 and Figures 1A, 1B, and 4), between the outlets 86 of the channel 82 and between the first and second electrode sets 14, 16 and 16, 18 (page 1 lines 27-29; page 2 lines 6-7; and Figure 1A).

Further, the present invention relates to a biosensor 10 (page 1 line 14). The biosensor 10 comprises a support 12 having first and second ends 28, 30 (page 1 lines 14-15; page 3 lines 12-16, page 4 lines 21-22; and Figure 2) and electrodes 14, 16, 18 positioned on the support 12 (page 1 lines 14-16; page 3 lines 1-3 and 26-27; page 4 lines 11-15; and Figures 2-4). The electrodes 14, 16, 18 cooperate with one another to define electrode arrays 76, 78 situated adjacent to the first end 28 of the support 12 (page 1 lines 16-17 and 21-22; page 4 lines 19-22; and Figures 2 and 3. The biosensor 10 further comprises a spacer 20 having individual first, second, and third members 40, 42, 44 (page 2 lines 20-23; page 4 line 28 to page 5 line 2; and Figure 2), and a cover 22 (page 1 line 18; page 2 lines 15-16; and Figures 1A, 1B and 2). The cover 22 cooperates with the support 12 to define a capillary channel 82 extending between the three members 40, 42, 44 (page 1 lines 20-21; page 2 lines 20-23 and 30-33; page 6 lines 6-11; and Figures 1A, 1B, and 4). The channel 82 has an inlet 84 positioned between the second and third members 42, 44 (page 6 lines 1-11; page 10 lines 11-14 and Figures 1A and 2) adjacent to the first end of the support (page 1 lines 20-21 and Figures 1A and 4) and spaced-apart first and second opposite outlets 86 (page 6 lines 1-6 and Figures 1A, 1B and 2). The first opposite outlet 86 is positioned between the first and second members 40, 42 and the second opposite outlet 86 being positioned between the first and third members 40, 44 (page 6 lines 2-3 and 6-9 and Figures 1A, 1B, 2 and 4). Each electrode array 76, 78 is positioned in the channel 82 adjacent to one of the opposite outlets 86 (page 1 lines 21-22; page 5 lines 3-5; page 6 lines 9-11; and Figures 1B and 2).

## ISSUES

The issues on appeal are whether or not the pending claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention and whether or not the pending claims are anticipated by Nankai (USPN 5,120,420).

## GROUPING OF CLAIMS

Claims 6, 10-15, and 21-26 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 10-15, and 21-26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nankai (USPN 5,120,420).

## ARGUMENT

Claims 6, 10, 15, and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

For purposes of 35 U.S.C. 112, second paragraph, words in claims are to be given their broadest reasonable interpretation consistent with the specification where the patent has not yet issued and the applicant has an opportunity to change them. In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (1971). The interpretation must be reasonable, since words or terms have to be given the meaning called for by the specification of which they form a part. In re Rovka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See also, MPEP 2111 - 2111.01.

1. The Examiner has asserted that Claim 24 is confusing with respect to the recitation of “a support having first and second ends”.

It is submitted that the Examiner's interpretation of the phrase "a support having first and second ends" as being unclear is not reasonable. In making that determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part. Claim 24 and the specification each recite "first and second ends" of a support in a manner that reasonably apprizes those of skill in the art of its scope.

Specifically, the specification defines an embodiment of the substrate as having "first and second ends" (page 1 lines 14-15). Still further, the specification describes the substrate of Figures 2 and 3 including a "first surface 24 . . . a second surface 26 . . . opposite first and second ends 28, 30 and opposite edges 32, 34 extending between the first and second ends 28, 30" (page 3 lines 12-15). Figures 1A and 2 illustrate opposite ends and the substrate 12.

As such, it is submitted that the specification and claims use the term "first and second ends" in a manner consistent with their ordinary meaning given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made and therefore meet the requirements under Section 112, second paragraph.

2. The Examiner has asserted that Claim 24 is unclear with respect to the phrase "electrode array". Specifically, the Examiner asserts that it is unclear to define two pairs of electrodes and call it an array.

It is submitted that the Examiner's interpretation of the phrase "electrode array" as being unclear is not reasonable. In making that determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part.

A review of Claim 24 as well as the specification as filed, demonstrates that the phrase "electrode array" is defined in a manner that is consistent with its ordinary meaning and is well understood by ordinary practitioners in the field of biosensors.

Attention is first directed to the specification. The specification defines the substrate as supporting two spaced-apart electrode arrays (page 2 lines 20-21). Further, it

teaches that “electrodes 14, 16, 18 cooperate with one another to define first and second electrode arrays 76, 78 and leads 80 that extend away from the first and second arrays 76, 78” (page 4 lines 19-21). The drawings illustrate electrode arrays 6, 78 in Figures 1B and 2. As such, “electrode arrays” are described both in the text of the application as well as the drawings. It is submitted that the use of the phrase “electrode arrays” in the text of the specification as well as by reference in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

Additionally, even if it is found that the term “array” is not well known, a claim should not be rejected as indefinite if the patent applicant merely uses new terminology that was formulated to describe an aspect of the invention. It is a fundamental principle under Section 112, second paragraph; the inventors may act as their own lexicographers. *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F. 2d 881, 221 USPQ 1025, 1031 (Fed. Cir. 1984); *Fromson v. Advance Offset Plate, Inc.*, 720 F. 2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

Thus, a claim may not be rejected solely because of the type of language used by an applicant to define the subject matter for which patent protection is sought. The specification and drawings are replete with description of electrode arrays (page 1 lines 16-17 and 32-33, page 2 lines 20-21; page 4 lines 19-27; page 5 lines 3-5; page 6 lines 9-12, 17-19, 25-27; page 10 lines 8-11 and 19-22; and Figures 1B, 2, and 4 ). Applicants have described “electrode arrays” both in the text of the application as well as the drawings.

Accordingly, the phrase “electrode arrays” is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

3. The Examiner has asserted that Claim 24 is unclear with respect to the recitation of “a spacer having individual members”.

It is submitted that the Examiner's interpretation of the phrase "a spacer having individual members" as being unclear is not reasonable. In making that determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part.

A review of Claim 24 as well as the specification as filed, demonstrates that the phrase "a spacer having individual members" is defined in a manner that is consistent with its ordinary meaning and is well understood by ordinary practitioners in the field of biosensors.

As best illustrated in Figure 2, the spacer substrate 20 is described as having a first member 40 and second and third members 42, 44 spaced-apart from the first member 40 (page 4 lines 28-30). Additionally, the specification recites that when the spacer substrate 20 is coupled to the support 12, the electrode arrays 76, 78 are positioned to lie between the first member 40 and the second and third members 42, 44 (page 5 lines 3-5). As such, the phrase "a spacer having individual members" is supported in the text of the specification as well in the drawings and is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

The Examiner recommended claiming 2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers. As discussed above, there is support in the specification and Figure 2 for first, second and third members 40, 42, 44. Accordingly, support exists in the specification and drawings for the term "members", and a limitation listing the exact number is not necessary for purposes of 35 U.S.C. 112, second paragraph.

As such, the phrase "a spacer having individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

4. The Examiner has asserted that Claim 24 is unclear with respect to the phrase “a cover cooperating with the support to define a capillary channel extending between the individual members”.

It is submitted that the Examiner’s interpretation of the phrase “a cover cooperating with the support to define a capillary channel extending between the individual members” as being unclear is not reasonable. In making that determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part.

The Examiner asserted that “the cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this.”

As discussed above, there is support in the specification and Figure 1A, 1B, and 2 for a cover, a support, and first, second and third members 40, 42, 44. Support exists in the specification (page 1 lines 18-19 and 27-28) and drawings (Figures 1A and 1B) for a channel defined by the cover and the support. Support also exists in the specification (page 6 lines 6-11) and drawings (Figures 1A and 1B) for the phrase “a capillary channel extending between the individual members”.

Further, it is submitted that Claim 24 does in fact sufficiently define the metes and bounds of the channel. The channel is defined by the cover and support and extends between the individual members. Thus, not only are all of the terms of the phrase definite, but the phrase also shows the communication between each object.

As such, the phrase “a cover cooperating with support to define a capillary channel extending between the individual members” is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

5. The Examiner has asserted that Claim 24 is unclear with respect to the phrase “the channel having opposite ends”. The Examiner has asserted that it is unclear and indefinite to claim a channel having opposite ends.

Claim 24 does not recite a channel having opposite ends, but rather recites a channel having opposite outlets. It is submitted that the phrase “the channel having opposite outlets” is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

6. Examiner has asserted that Claim 24 is unclear with respect to the phrase “a concave inlet extending from the first end of the support and being positioned between opposite ends of the channel”. The Examiner has asserted that it is unclear and indefinite to claim “a concave inlet extending from a first end, what first end? Where on the support?”

It is submitted that the Examiner’s interpretation of the phrase “a concave inlet extending from the first end of the support and being positioned between opposite ends of the channel” as being unclear is not reasonable. In making that determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part.

As discussed above in point 1, it is submitted that the phrase “first end of the support” is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph. Support exists in the specification and drawings for the term “concave inlet” (page 6 lines 1-2; page 10 lines 11-14 and Figure 1A). As such, it follows that the phrase “a concave inlet extending from the first end of the support”, is also definite for purposes of Section 112, second paragraph.

The Examiner further questioned whether the inlet is the channel and to require definition of “the positioning and orientation of the inlet with respect to the channel”.

Claim 24 recites that the channel has “a concave inlet”. It is submitted that the use of the term “inlet” with respect to a channel is in accordance with its ordinary meaning that is well understood by ordinary practitioners in the field of biosensors. Further, Claim 24 recites that this inlet extends from “the first end of the support”. This provides sufficient description regarding the inlet’s positioning and orientation on the biosensor. Still further, Claim 24 recites that the inlet is positioned between the opposing outlets of the channel. As such, the inlets positioning and orientation with respect to the channel as a whole is defined.

As such, it is submitted that the phrase “a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel” is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

7. Examiner has asserted that Claim 24 is unclear with respect to the phrase “each electrode array being positioned in the channel adjacent to one of the opposing ends”.

It is submitted that the Examiner’s interpretation of the phrase “each electrode array being positioned in the channel adjacent to one of the opposing ends” as being unclear is not reasonable. In making that determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part.

The Examiner rejected the phrase “opposing ends” and made the comment “Adjacent to what?” As discussed above, Claim 24 does not recite opposing ends of a channel, but rather opposing outlets. Still further, it is submitted that it is sufficiently clear from the text of the claim, the specification, and drawings that each electrode array is positioned in the channel adjacent to one of the opposing outlets of the channel (page 1 lines 27-29; page 2 lines 6-7; and Figures 1A and 4). As such, the phrase “each electrode array being positioned in the channel adjacent to one of the opposing ends” is sufficiently clear from both its description in the specification as well as its ordinary

meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Further, the Examiner made the comment that the “electrode arrays are just two electrodes connected to each other to make a couple or pair of electrodes not an array”. Support in the specification and drawings for the term “array” is discussed above in section (2).

In light of the above discussion, it is submitted that Claim 24 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Regarding Claim 25:

1. The Examiner has asserted that Claim 25 is unclear with respect to the phrase “a support having first edge”. Specifically, the Examiner has asserted that it is unclear to define an edge on a support that has six sides.

It is submitted that the Examiner’s interpretation of the phrase “a support having first edge” as being unclear is not reasonable. In making that determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part.

A review of Claim 25 as well as the specification as filed, demonstrates that the phrase “first edge” is used in a manner that is consistent with its ordinary meaning in the field of biosensors. In that regard, attention is directed to the specification, which describes a substrate 12 that includes edges. Figures 1A and 2 also illustrate edges of the support.

As such, it is submitted that the specification and claims use the term “first edge” in a manner consistent with its ordinary meaning given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made and therefore meet the requirements under Section 112, second paragraph.

2. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "first and second electrode sets positioned on the support spaced apart from one another".

It is submitted that the Examiner's interpretation of the phrase "first and second electrode sets positioned on the support spaced apart from one another" as being unclear is not reasonable. In making that determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part.

The specification defines an embodiment of the substrate as having first and second electrode sets positioned on the support spaced apart from one another (page 1 lines 23-26; page 3 lines 1-3 and 26-27; page 4 lines 11-15; page 9 lines 4-6; and Figures 2-4). Accordingly, it is submitted that it is sufficiently definite to recite that the sets are positioned on the support.

The Examiner requested details on where on the support and the orientation of the electrodes. Claim 25 does in fact recite that the electrode sets are positioned on the support spaced apart from one another and that the inlet of the channel is positioned between the first and second electrode sets. As such, it is submitted that Claim 25 sufficiently demonstrates communication between each object in a clear and concise manner.

In light of the above, the use of the phrase "first and second electrode sets positioned on the support spaced apart from one another" is sufficient to meet the requirements under Section 112, second paragraph.

3. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "a spacer having individual members".

It is submitted that the Examiner's interpretation of the phrase "a spacer having individual members" as being unclear is not reasonable. In making that

determination, it is submitted that the Examiner has failed to give the terms the meaning called for by the specification of which they form a part.

A review of Claim 25 as well as the specification as filed, demonstrates that the phrase “a spacer having individual members” is defined in a manner that is consistent with its ordinary meaning and is well understood by ordinary practitioners in the field of biosensors.

As best illustrated in Figure 2, the spacer substrate 20 is described as having a first member 40 and second and third members 42, 44 spaced-apart from the first member 40 (page 4 lines 28-30). Additionally, the specification recites that when the spacer substrate 20 is coupled to the support 12, the electrode arrays 76, 78 are positioned to lie between the first member 40 and the second and third members 42, 44 (page 5 lines 3-5). As such, the phrase “a spacer having individual members” is supported in the text of the specification as well in the drawings and is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

The Examiner recommended claiming 2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers. As discussed above, there is support in the specification and Figure 2 for first, second and third members 40, 42, 44. Accordingly, support exists in the specification and drawings for the term “members”, and a limitation listing the exact number is not necessary for purposes of 35 U.S.C. 112, second paragraph.

As such, the phrase “a spacer having individual members” is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

4. The Examiner has asserted that Claim 25 is unclear with respect to the phrase “a cover having a second edge and extending across the first and second electrode sets”.

It is submitted that the Examiner's interpretation of the phrase "a cover having a second edge and extending across the first and second electrode sets" as being unclear is not reasonable.

First, Claim 25 does not recite the phrase asserted by the Examiner. Instead, the Claim 25 recites "a cover having a second edge, the cover extending across the first and second electrode sets". As such, the Examiner's assertion "it is more than likely that the edge is not extended across the first and second electrode", is moot.

Second, it is submitted that the Examiner has failed to give the terms of the phrase the meaning called for by the specification of which they form a part.

A review of Claim 25 as well as the specification as filed, demonstrates that the term "second edge" is used in a manner that is consistent with its ordinary meaning that is well understood by ordinary practitioners in the field of biosensors.

In that regard, attention is directed to the specification and Figures 1A, 1B and 2, which defines an embodiment of the cover 22 with edges. As such, the phrase "a cover having a second edge" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Accordingly, it is submitted that the phrase "a cover having a second edge, the cover extending across the first and second electrode sets" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

5. The Examiner has asserted that Claim 25 is unclear with respect to the phrase "the cover cooperating with support to define a generally linear capillary channel extending between the individual members".

It is submitted that the Examiner's interpretation of the phrase "the cover cooperating with support to define a generally linear capillary channel extending between the individual members" as being unclear is not reasonable.

First, the phrase "generally linear channel" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph. In that regard, a generally linear capillary channel is described in the specification (page 1 line 28; page 6 lines 1-2). Additionally, the drawings, Figure 1A, for example, illustrates this generally linear design. As such, the use of the phrase "generally linear channel" in the text of the specification as well in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

Next, the Examiner asserts that "the cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this".

As discussed above, there is support in the specification and Figure 1A, 1B, and 2 for a cover, a support, and first, second and third members 40, 42, 44. Support exists in the specification (page 1 lines 18-19 and 27-28) and drawings (Figures 1A and 1B) for a channel defined by the cover and the support. Support also exists in the specification (page 6 lines 6-11) and drawings (Figures 1A and 1B) for the phrase "a capillary channel extending between the individual members".

Further, it is submitted that Claim 25 does in fact sufficiently define the metes and bounds of the channel. The channel is defined by the cover and support and extends between the individual members. Thus, not only are all of the terms of the phrase definite, but the phrase also shows the communication between each object.

As such, the phrase "the cover cooperating with the support to define a generally linear capillary channel extending between the individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its

description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

6. The Examiner has asserted that Claim 25 is unclear with respect to the phrase “the channel having opposing first and second ends and an inlet aligned with the first edge of the support and the second edge of the cover”.

It is submitted that the Examiner’s interpretation of the phrase the channel having opposing first and second ends and an inlet aligned with the first edge of the support and the second edge of the cover” as being unclear is not reasonable.

First, Claim 25 does not recite the phrase asserted by the Examiner. Instead, Claim 25 recites that the channel has “opposing first and second outlets”. As such, the Examiner’s assertion “How does a channel have opposing first and second ends if it is not a totally closed channel, sounds more like a chamber, it is unclear and indefinite”, is moot.

Second, the Examiner has asserted that “First edge of the support and the second edge of the cover is unclear and indefinite, where are the spacers in this orientation?” As discussed above in points 1 and 4, the phrases “first edge of the support” and the “second edge of the cover” are fully supported by the specification and drawings and as such their respective meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Regarding the location of the spacer, Claim 25 recites that the cover cooperates with the support to define a generally linear capillary channel extending between the individual members. As such, it is submitted that Claim 25 sufficiently demonstrates communication between each object in a clear and concise manner.

As such, the meaning of the phrase “the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover” is sufficiently clear from both its description in the specification as well as

its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

7. The Examiner has questioned to what the phrase “between the ends of the channel” in claim is referring.

As discussed above in point 6, Claim 25 does not recite the phrase asserted by the Examiner. Instead, Claim 25 recites that the channel has “opposing first and second outlets”. As such, the Examiner’s question is moot.

It is submitted that the phrase “between the outlets of the channel” is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

8. The Examiner has asserted that the phrase “and between the first and second electrode sets” is unclear and indefinite. Specifically, the Examiner has asserted that “The biosensor needs to show communication between each object in a clear and concise manner in which one of ordinary skill in the art would be able to have a clear understanding of the invention.

It is submitted that the Examiner’s interpretation of the phrase “and between the first and second electrode sets” as being unclear is not reasonable.

In that regard, Claim 25 recites “first and second electrode sets positioned on the support spaced-apart from one another”, satisfying communication between the electrode sets and the substrate. Next Claim 25 recites a cover “extending across the first and second electrode sets”, satisfying communication between the electrode sets and the cover. Still further, Claim 25 recites an inlet to the channel positioned “between the first and second electrode sets”, satisfying communication between the electrode sets and the channel. As discussed above, the channel itself is defined by the cover and support and extends between members of the spacer. Accordingly, it is

submitted that the electrode sets are defined by Claim 25 with reference to each of the elements – substrate, cover, and spacer - of the claim.

As such, the phrase “between the first and second electrode sets” is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

In light of the above discussion, it is submitted that Claim 25 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Regarding Claim 26:

The Examiner has rejected Claim 26 as having the same problems as mentioned in Claim 24 and Claim 25. The Examiner asserts only that it is entirely unclear and indefinite as a whole.

To the extent that the rejection overlaps claims 24 and 25, it is submitted that the arguments made above with respect to Claims 24 and 25 apply to Claim 26.

Additionally, it is noted that Claim 26 recites a channel having “spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members, each electrode array being positioned in the channel adjacent to one of the opposite outlets”. In light of the above discussion with reference to Claims 24 and 25, it is submitted that Claim 26 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Accordingly, Claims 24-26 are sufficiently definite for purposes under Section 112, second paragraph. Claim 6 depends from Claim 24, claims 10-15 depend from Claim 25, and claims 21-23 depend from Claim 26.

Appellant respectfully contends that the claims of the present invention comply fully with the requirements of 35 U.S.C. 112, second paragraph. Reversal of the rejection based on that statutory section is requested.

Claims 6, 10-15, and 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nankai et al. (USPN 5,120,420).

Nankai et al. discloses a biosensor that includes a base plate having an electrode system. By integrating with a cover, a space including the reaction layer is formed and an introducing port for introducing a sample solution into the space and a discharge port for discharging a gas in the space by inflow of the sample solution. See, Column 3 lines 5-15.

The Examiner asserts that “with regards to claim [sic.] 4-6, the claims only require that the spacer have members. The broadest possible reading on this would be a spacer layer that has members formed from an original spacer (fig. 4). In Fig. 4 there is a U shaped spacer.” It is first noted that claims 4 and 5 were previously cancelled without prejudice or disclaimer of the subject matter recited therein and are no longer pending in the application. As such, the rejection will not be addressed with respect to the cancelled claims 4-5. It is further noted that claim 6 depends from independent Claim 24.

Independent claims 24, 25, and 26 each recite “individual members”. It is noted that the U shaped spacer of Figure 4 in Nankai et al. lacks individual members. As such, Nankai et al. cannot be said to anticipate the biosensors of Claim 24, 25, and 26.

Reversal of the rejection of the claims under 35 U.S.C. 102(b) is requested.

No rejection under 35 U.S.C. 103(a) is pending. The Examiner, however, in Response to Arguments in the pending Office Action made a statement regarding

obviousness. The Examiner asserted that case law applied in the rejection states that “it would have been obvious . . . to change the shape of an object. The spacer of Nankai performs the same function of the spacer in the instant application, it provides 2 sides of a channel in which a fluid flows there through, the other sides of the channel are provided by the cover and the substrate”. What follows, therefore, is a response to the Examiner’s apparent obviousness concerns over Nankai et al.

It is true that Nankai et al. describes a spacer and that the claims of the present invention recite a spacer. It is also true that spacers are known to function by providing sides of a channel. It is not the case, however, that spacers are the same and that their configuration changes are obvious, as asserted by the Examiner. It is the configuration of the spacer in conjunction with the substrate, electrodes, and the cover, which provides a unique and unobvious biosensor configuration as it relates to independent claims 24-26.

A key difference between the biosensors of Nankai et al. and Claims 24-26 relates to the flow pattern of the liquid sample within the biosensors (see page 2 lines 30-34 and page 10 lines 18-22 of the specification). In that regard, attention is directed to each of the Figures of Nankai et al., where it is illustrated that a resulting liquid flow pattern would be essentially forward moving. There is certainly no opposing dual-directional flow taught or suggested by Nankai et al. In fact, Nankai et al. teaches away from such an arrangement.

In that regard, attention is directed to Nankai et al. at column 5 lines 19-36:

When the introducing port at the tip of the glucose sensor constructed as described above is brought into contact with a glucose standard solution (200 mg/dl), which is a sample solution, the sample solution is introduced into the inside through the introducing port 10. In this case, the air in the space 8 is rapidly discharged through the discharge port 11 and at the same time, the space is filled up with the sample solution up to near the discharge port. As such, the sample solution rapidly spreads onto the electrode surface to fill up the space so that any remaining air bubbles are not noted.

This is believed to be because the sample solution would flow into *one direction* by providing the introducing port and the discharge port and due to the hydrophilic high molecular substance layer previously formed on the electrodes, wetting on the electrode surface would be improved so that the gas is smoothly exchanged with the liquid. (Emphasis added)

As such, Nankai et al. teaches dual-directional flow as being worse than one-directional flow achieved by its disclosed biosensor configuration.

It is important to note that each of the biosensors of claims 24-26 is configured for and operate using opposing dual-directional flow of a liquid sample applied to its respective inlet.

For example, Claim 24 recites “a capillary channel extending between the individual members, the channel having opposing outlets and a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel”. With an inlet positioned between opposing outlets, opposing dual directional flow of a liquid introduced into the inlet is achieved.

Claim 25 recites “a generally linear capillary channel extending between the individual members, the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover, between the outlets of the channel, and between the first and second electrode sets”. Again, with an inlet positioned between opposing outlets, opposing dual directional flow of a liquid introduced into the inlet is achieved.

Claim 26 recites a channel “extending between the three members and having an inlet positioned between the second and third members adjacent to the first end of the support and spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members”. Again, opposing dual directional flow of a liquid introduced into the inlet is achieved.

As such, Nankai et al.'s U-shaped spacer teach away from the biosensors recited by Claims 24-26 and cannot be said to render the pending claims obvious.

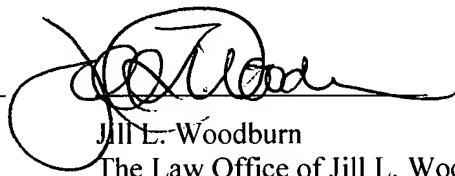
It is respectfully submitted that the claimed invention is not anticipated by Nankai et al. and further that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made.

In light of the above, reversal of the rejection of the claims under 35 U.S.C. 112, second paragraph and 35 U.S.C. 102(b) leading to allowance of the claims is requested

Respectfully submitted,

Date:

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## APPENDIX OF CLAIMS IN APPEAL

Claims 1-5 (Cancelled).

Claim 6 (Previously presented): The biosensor of claim 24 wherein the individual members of the spacer include spaced-apart first, second and third members and the channel extends between the first, second, and third members.

Claims 7-9 (Cancelled).

Claim 10 (Previously presented): The biosensor of claim 25 wherein the individual members include a first member extending between the outlets of the channel.

Claim 11 (Previously presented): The biosensor of claim 10 wherein the members include a second member positioned between one outlet and the inlet and a third member positioned between the opposite outlet and the inlet.

Claim 12 (Previously presented): The biosensor of claim 10 wherein the members include second and third members spaced-apart from the first member and the channel extends between the first, second, and third members.

Claim 13 (Previously presented): The biosensor of claim 25 wherein the cover and the support are formed to include a notch in general alignment with one another.

Claim 14 (Original): The biosensor of claim 13 wherein each notch is generally concave in shape.

Claim 15 (Original): The biosensor of claim 13 wherein the inlet intersects the notches.

Claims 16-20 (Cancelled).

Claim 21 (Previously presented): The biosensor of claim 26 wherein the cover and the support are formed to include a notch in general alignment with one another.

Claim 22 (Previously presented): The biosensor of claim 21 wherein each notch is generally concave in shape.

Claim 23 (Previously presented): The biosensor of claim 21 wherein the inlet intersects the notches.

Claim 24 (Previously presented): A biosensor comprising a support having first and second ends,

electrodes positioned on the support, the electrodes cooperating with one another to define electrode arrays situated adjacent to the first end, a spacer having individual members, and a cover cooperating with the support to define a capillary channel extending between the individual members, the channel having opposing outlets and a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel, each electrode array being positioned in the channel adjacent to one of the opposing outlets.

Claim 25 (Previously presented): A biosensor comprising:  
a support having a first edge,  
first and second electrode sets positioned on the support spaced-apart from one another,  
a spacer having individual members, and  
a cover having a second edge, the cover extending across the first and second electrode sets, the cover cooperating with the support to define a generally linear capillary channel extending between the individual members, the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover, between the outlets of the channel, and between the first and second electrode sets.

Claim 26 (Previously presented): A biosensor comprising  
a support having first and second ends,  
electrodes positioned on the support, the electrodes cooperating with one another to define electrode arrays situated adjacent to the first end, a spacer having individual first, second, and third members, and a cover cooperating with support to define a capillary channel, the channel extending between the three members and having an inlet positioned between the second and third members adjacent to the first end of the support and spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members, each electrode array being positioned in the channel adjacent to one of the opposite outlets.